M700VET Veterinary Pulse Oximeter

User's Manual

Guangdong Biolight Meditech Co., Ltd.

Address: No.2 Innovation First Road, Technical Innovation Coast,

Hi-tech Zone, Zhuhai , P.R.China

http://www.blt.com.cn

J/M700-041-2011A3

Preface

Thank you for using M700 Veterinary Pulse oximeter.

In order to enable you to skillfully operate the pulse oximeter as soon as possible, when you install and use this instrument for the first time, it is imperative that you read carefully all the information that accompanies this instrument.

Based on the need to improve the performance and reliability of the parts and the whole instrument, we sometimes will make some amendments to the instrument (including the hardware and software). As a result, there might be cases of discrepancies between the manual and the actual situation of products. When such discrepancies occur, we will try our best to amend or add materials. Your comments and suggestions are welcome.

Our liaison-way:

Address: No.2 Innovation First Road, Technical Innovation Coast,

Hi-tech Zone, Zhuhai , P.R.China

Post code: 519085

Fax: +86-756-3399919

Toll-free consultation hot line: +86-400-8818-233

Statement

This manual contains exclusive information protected by copyright laws and we reserve its copyright. This manual is a reference book for operation, maintenance and repair, and it is prohibited to disclose it to others.

Without written approval of manufacturer no parts of this manual shall be photocopied, Xeroxed or translated into other languages.

The contents contained in this manual are subject to amendments without notification.

The version number of manual is: A3

Liabilities of the Manufacturer

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument.

- All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.
- The electrical safety status at the installation site of the instrument conforms to the national standards;
- The instrument is used in accordance with the operation procedures.

Signs in this manual:

Warning: Means it must be strictly followed so as to prevent the operator or the patient from being harmed.

Caution: Means it must be followed so as not to damage the instrument.

Note: Important information or indications regarding the operation or use.

CONTENTS

Chapter 1 Safety Information 1-1

1.1Warnings 1-1

1.2 Cautions 1-3

Chapter 2 General Introduction 2-1

2.1 How to Use this Manual 2-1

2.2 Intended Use for the oximeter 2-1

2.3 Product restriction 2-1

2.4 Explanation of Symbols 2-1

Chapter 3 Appearance and structure 3-1

3.1 Symbols , Displays and Indicators 3-1

3.2 List of Components 3-4

3.3 Installing the Batteries 3-4

3.4 Installing the SpO_2 probe 3-5

Chapter 4 Operation Instructions 4-1

4.1 Preparations before the Use of the Oximeter 4-1

4.2 General Operations 4-2

4.3 Prompt info 4-4

Chapter 5 Performance Considerations 5-1

5.1 Oximeter Performance Considerations 5-1

5.2 Sensor Performance Considerations 5-2

5.3 Loss-of-pulse signal Considerations 5-2

5.4 Ambient light source Considerations 5-2

5.5 Patients' influence 5-3

Chapter 6 System Maintenance 6-1
6.1 Oximeter 6-1
6.2 Oximeter Sensor 6-2
6.3 Sketch Map of electrical Mechanism 6-2
6.4 Troubleshooting 6-2
6.5 Periodic Safety Checks 6-6
6.6 Warranty Provisions 6-7
Chapter 7 Specifications 7-1
7.1 Performance 7-1
7.2 Electrical 7-1
7.3 Environmental Conditions 7-2
7.4 Physical Characteristics 7-2
7.5 Sensors 7-3
7.6 Classification 7-3
Chapter 8 Accessories 8-1
Appendix A: Guidance and Manufacture's Declaration of EMC 1

Chapter 1 Safety Information

1.1 Warnings

Warning:

- **The oximeter is intended for Veterinary use only. Do not use on human patients.**
- **Explosion hazard: Do not use the oximeter in the presence of flammable anesthetics mixture with air, oxygen, or hydrogen.**
- **The oximeter is a prescription device to be operated only by trained personnel. When the oximeter is in use, there should not be any great power appliances as high voltage cables, X-ray machine, ultrasound equipment and electrizer in use nearby.**
- **Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.**
- **The oximeter is not designed for the sterilized room. The oximeter is not designed for outdoor use.**
- **This oximeter does not have alarm function; please do not use this product in the environment where alarm is required.**
- **The oximeter should be handled with care so as to avoid shocks and falls.**
- **When the oximeter is in use, it must be ensured the batteries have sufficient capacity; otherwise there might be such phenomena as starting-up abnormalities or inaccurate measurement data, etc.**
- **To avoid the damage of keyboard, please do not use such pointed objects as pen point or nails for pressing operation, otherwise it might cause permanent damage to the surface of the keyboard.**
- **Do not make any clinical judgments based solely on the oximeter. The oximeter is intended only as an adjunct**

in patient assessment. It must be used in conjunction with clinical signs and symptoms, as well as doctor's diagnoses.

- **To ensure accurate performance and prevent device failure, do not expose the oximeter to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.**
- **When the oximeter is in use, the medical personnel shall not leave the operating site, but rather observe the patient closely; when it is necessary, turn off the power or remove the sensor so as to ensure the safety of the patient. In case of accidents during use, the machine must be switched off immediately for examination.**
- **According to IEC60601-1:1995, the oximeter belongs to the BF type equipment for internal use and is safe and reliable .If it is desired for combined use with other electrizer or high-frequency operating or high-frequency equipment, there might be such phenomena as incorrect measuring data and burning.**
- **Measurements and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.**
- **The use of accessories, sensors, and cables other than those specified may result in increased emission, low anti-disturbance and/or create invalid readings of the oximeter. It is advised to check it at least once a month.**
- **As with operation of all other medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **To ensure patient safety, do not place the oximeter in any position that might cause it to fall on the patient.**
- **Not use rechargeable batteries, only use alkaline battery: 1.5V; AA Size; LR6 according to IEC 60086-2.**
- **In order to prevent the occurrence of "tissue necros due to crush" caused by the prolonged use of oximeter, every**

four to six hours the position of the SpO2 sensor should be checked to check the dosimeter's affect on the skin, whether there is erythema or stimulation, move the oximeter and place it on a different location.

- **No use-serviceable parts inside, before servicing to authorized representative or manufacturer.**

1.2 Cautions

Caution: In order to have more accurate measurements of SpO_2 and PR, the oximeter should be used in quiet and comfortable environment.

Chapter 2 General Introduction

2.1 How to Use this Manual

All users should read this manual thoroughly. More experienced users of the oximeter can refer directly to the topics for the information they require.

2.2 Intended Use for the oximeter

The veterinary pulse oximeter is indicated for spot checking of functional arterial oxygen saturation (SpO2) and pulse rate of animals.The oximeter is intended to be used in special procedure labs and other areas of a veterinary hospital or clinic where veterinary monitoring systems are needed.

2.3 Product restriction

This product has no restriction.

2.4 Explanation of Symbols

	Type BF equipment (Refer to IEC 60601-1:1995)
	Attention! Please refer to this manual.
	Date of Manufacture.
	Power On/Off Button

	Up/Down Button (Use it with Choice button)
	Up/Down Button (Use it with Choice button)
	Choice Button
	Switch On/Off Button for pulse sound
%SpO_2	The display region of SpO_2 reading (the unit is **%**)
/Min	The display region of Pulse rate reading (the unit is **bpm**)
Low Perfusion	Low Perfusion indication
	Non-Alarm (The device does not have alarm function)
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.

Chapter 3 Appearance and structure

3.1 Symbols , Displays and Indicators

3.1.1 Front Panel Description

Fig. 1 Front Panel Description

① Power indicator light

② The display region of SpO_2 reading (%)

③ The display region of Pulse rate reading (bmp)

④ Pulse Amplitude indicator (Blip bar)

⑤ Selection button

⑥ Up/Down button

⑦ On/Off button for pulse sound

⑧ Up/Down button

⑨ Power on/off button

⑩ Low Perfusion indication

3.1.2 Rear Panel Sketch Map

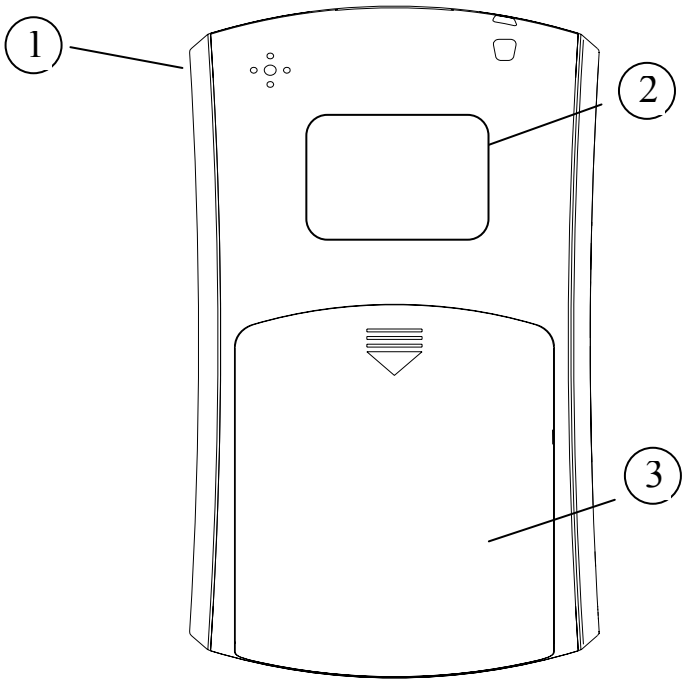

Fig.2 Rear Panel sketch map

① Buzzer

② Label

③ Battery Cover

3.2 List of Components

Table 1 List of Components

Serial number	Item	Quantity
1	Oximeter	1
2	SpO_2 sensor	1
3	User's manual	1
4	Certificate of quality	1
5	Warranty card	1
6	AA battery	4

3.3 Installing the Batteries

Refer to figure 3, Pull the battery compartment latch downward, toward the button of the oximeter, and remove the battery access door, Install four "AA" batteries, oriented as shown in Figure3. Close the battery access door. When installing batteries, install the negative end of each battery first, press the terminal spring until the positive terminal clears the positive spring, and press the battery downward into place. To remove the batteries, reverse the installation process, remove the positive end of each battery first.

Warning: When the oximeter is not in use for a long time, the battery should be removed from it. Dispose of battery in accordance with local ordinances and regulations.

Caution: Don't use lithium batteries with the oximeter, Lithium batteries will damage the oximeter.

Caution: Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the oximeter may occur.

Caution:Do not mix alkaline "AA" batteries with rechargeable batteries. When replacing batteries, replace with four fresh (new) batteries. Do not mix used and new batteries.

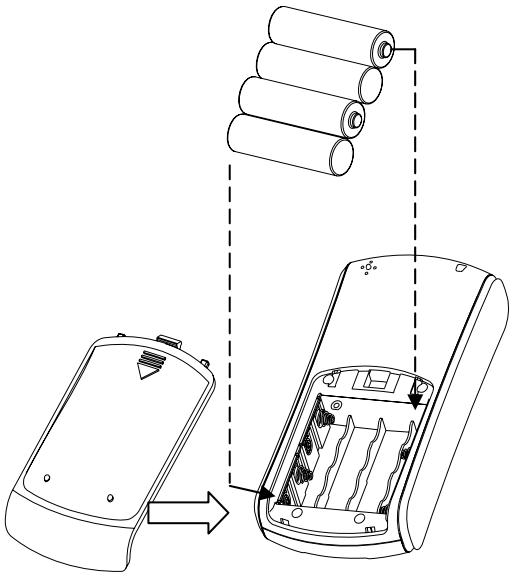

Fig.3 Installing Battery

3.4 Installing the SpO_2 probe

Install the probe as shown in Fig. 4. Keep the indentation of the probe consistent with the front panel of the oximeter and then plug it into the socket.

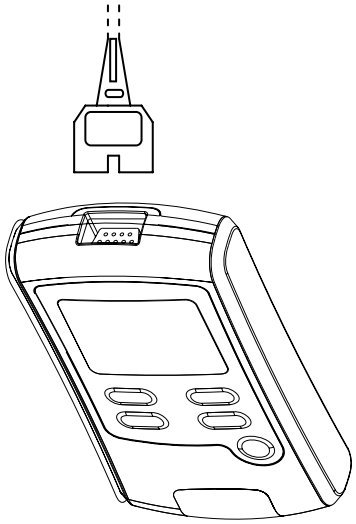

Fig 4 Installing the SpO_2 Probe

Warning:

- **Before use, the operator must ensure the compatibilityies of the oximeter, sensor and extension cables; otherwise, this may lead to the burning of patients; do not use damaged sensor or extension cable. Do not soak the sensor into water or make it wet, otherwise it may be damaged.**
- **If the NIBP and SpO_2 are measured at the same time, please do not put the NIBP cuff and the SpO_2 sensor on the same extremity, this is because the NIBP measure -ment may block blood circulation, thus affect the SpO_2 measurement.**

Caution: If it is necessary to have additional clip to fix the tip sensor, the cable should be clipped instead of the oximeter. Please do not pull the oximeter cable with force.

Note:

- **Frequent movements of the sensor may lead to the measuring errors of the oximeter.**
- **When using SpO_2 sensor, care should be taken to shield external light sources, such as light of thermo therapy or ultraviolet heating light, otherwise the measurements may be disturbed. Under such conditions as shock, hypothermia, anemia or the use of blood vessel-activating drugs, and with the existence of such substances as carboxyhemoglobin, methemoglobin, methylene blue the result of the SpO_2 measurement will be possibly not accurate.**
- **Before use, the operator must identify the characteristics of patients, such as age, body weight the points on the body where the sensor is applied.**

Chapter 4 Operation Instructions

4.1 Preparations before the Use of the Oximeter

4.1.1 Unpacking the Case

Unpack the packaging case and contained in the case are the oximeter, SpO_2 sensor, batteries and such documents as User Manual (this Manual), warranty card, certificate of quality and packing list.

4.4.2 Preparation and Examination

1) It is advised that before each use ensure the functions of the oximeter are normal, and the function examinations can be conducted through normal animal or SpO2 simulator.
2) Make sure the SpO_2 probe is properly connected with the oximeter.
3) Ensure the temperature and humidity of this location is within the allowed range of the oximeter use.
4) Make sure within the proximity of the location there is no use of X ray, ultrasound devices or other electrical appliances that might give off radio frequency, power disturbances, which may produce disturbances to the oximeter; please remove the oximeter to a location free of disturbances or turn off the power of the above electrical appliances.
5) Select a sensor and clip that is appropriate for the patient.
6) Clean the sensor and sensor clip separately before and after each use.
7) Put the sensor on the tongue or ear of animal. The preferred sensor application site for canine, feline and equine animals is on the tongue,

with the sensor's optical components positioned on the center of the tongue. Alternatively, the sensor and clip may be applied to the animal's lip, toe, ear, prepuce, or vulva.

Caution: In case it is necessary to add a clip to fix the sensor, the cable instead of the sensor itself should be clipped. Please note that the cable of sensor should not be pulled with force.

4.2 General Operations

4.2.1 Start-up and switch off of the oximeter

Press for about one second and release it immediately to turn on the power and the power indicator turns green and the oximeter is switched on. Press for one second and release it immediately, and the oximeter is switched off immediately.

When the oximeter is switched on, it gives off a "D" sound, and all the lights in the digital tube are on and the oximeter enters self-examinations status.

Caution: When the oximeter is started, if the indicating light or the digital display do not light up or there is no "D" sound and the results are the same after repeating several times, first check the battery capacities. If the battery capacities are sufficient, it might be something wrong with the the oximeter. Please do not use the oximeter and contact professional repairmen, local agency of the Company or the aftersales agent of the Company.

4.2.2 Operation

For normal operations, oximeter has the following modes:
1) If the oximeter probe is not plugged into the oximeter, or the probe has been plugged into the oximeter but no finger is inserted into the probe, the SpO_2 and PR flashes and displays ---, giving off "D-D" sound at intervals, and the oximeter will be automatically switched off in 120 seconds.
2) After the patient has been connected with the oximeter, the oximeter begins searching PR, SpO_2 and PR flash to display ---. If PR is searched, a PR sound is given off; if it is not searched, then after continuing to search for another 120 seconds it will be automatically switched off.
3）When measuring the data, SpO_2% and /Min respectively displays SpO_2 and PR. When the measuring data are stabilized, PR intensity indication and PR sound are synchronized. The pressing of will switch off or turn on PR sound.
4）when it is at low perfusion, the low perfusion indicating lights will light up.
5）Under the battery management mode , mean time mode or software version displaying mode，if there is no operation to buttons, in 15 seconds the oximeter will be automatically restored to its normal measuring mode.
6）When the battery capacity is exhausted, the oximeter will be automatically switched off in 5 minutes.

Note: The oximeter does not have alarm function.

Note:The oximeter does not provide automatic self-examination alarm signal and the operator has to use SpO_2 simulator for self-examination.

4.2.3 Button Operation

On/Off button, press to enter the working mode, then press it again to enter the Off status.

Press (MODE) to switch between normal measuring data display mode, battery management mode，SpO_2 Mean Time Adjustment mode and software version displaying mode; when it is in the measuring data display mode，SPO_2% displays SpO_2 value, /Min displays PR value; when it is in the battery management mode, SPO_2 displays "bAt", /Min displays LED light intensity level 1 to 5, in the SpO_2 Mean Time Adjustment mode, SPO_2 displays "AUE", /Min displays Mean Time 4，8 or 16，under software version displaying mode，UPr is displayed in the SPO2% region，and version number of current software is displayed in the /Min region.

In the normal measuring data display mode, press (◄) to tune down the PR sound, and press (►) to tune up the PR sound; in the battery management mode, press (◄) to decrease the light intensity of the LED, and press (►) to increase the light intensity of the LED; in the SpO_2 Mean Time Adjustment mode, press (◄) to decrease mean time, and press (►) to increase the mean time.

Press (🔇) to switch on or off the PR sound.

4.3 Prompt info

4.3.1 Sensor Off

The indication displays "---" with flashing frequency of 0.5 Hz, and gives off "D-D" sound at 25 seconds interval.

4.3.2 Batteries:

When the batteries are in low voltage, the power indicating light turns yellow and flashing with frequency of 0.5Hz, and gives off "D-D-D" sound at 25 seconds interval.

Caution: When the batteries have low capacities, there might be abnormal operations, such as all the lights in the digital tubes light up and "00" is displayed in the data display zone or other abnormal data, as well as such phenomena as continuous sounding of the buzzer and abnormal start-up and switch-off of the oximeter. Therefore, when the batteries are in low voltage, please replace batteries as soon as possible.

Chapter 5 Performance Considerations

Warning: Pulse oximetry readings and pulse signals can be affected by ambient environmental conditions, sensor application errors, and patient conditions. See the appropriate sections of the manual for specific safety information.

5.1 Oximeter Performance Considerations

1) Dysfunctional Hemoglobins

Dysfunctional hemoglobins such as arboxyhemoglobin, methemoglobin, and sulfhemoglobin, are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.

2) Anemia

Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may be hypoxic. Anemia treatment can improve arterial oxygen content. The oximeter may fail to provide a SpO_2 if hemoglobin levels fall below 5 gm/dl.

3) Saturation

The oximeter displays saturation levels between 35% and 100%. When the measuring data exceeds this range, some abnormalities may occur.

4) Pulse Rates

The oximeter displays pulse rates between 25 and 250 beats per minute. When a rate is lower than 25 times /min or higher than 250 times/min, some abnormalities may occur.

5.2 Sensor Performance Considerations

Inaccurate measurements can be caused by:

1）Incorrect application of the sensor;
2）Sensor is placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
3）Excessive patient movement;
4）Intravascular dyes, such as indocyanine green or methylene blue;
5）Externally applied coloring, such as nail polish or pigmented cream;
6）Failure to cover the sensor site with opaque material in an intense light environment;
7）Venous pulsation
8）Dysfunctional hemoglobin
9）Low perfusion

5.3 Loss-of-pulse signal Considerations

Loss-of-pulse signal can occur for the following reasons:

1）The sensor is applied too tightly or loosed
2）Defibrillation
3）A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
4）There is arterial occlusion proximal to the sensor
5）Poor peripheral perfusion
6）Loss of pulse/cardiac arrest

5.4 Ambient light source Considerations

Intense ambient light sources that can interfere with the performance of a SpO_2 sensor as following:

1）Surgical lights (especially those with a xenon light source)
2）Bilirubin lamps
3）Fluorescent lights

4）Infrared heating lamps
5）Direct sunlight

To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

5.5 Patients' influence

If interference due to patient activity presents a problem, try one or more of the following to correct the problem:

1）Verify that the sensor is properly and securely applied
2）Move the sensor to another site
3）Use a new sensor with fresh adhesive backing
4）Keep the patient still, if possible

Chapter 6 System Maintenance

Warning: Be sure the power is switched off before cleaning the oximeter or the sensor.

6.1 Oximeter

1）The most commonly used hospital cleaning agent and non-corrosive detergents can be used for cleaning the oximeter, but please be careful that many types of detergents must be diluted before use; Please use them according to the directions of the manufacturers of the detergents.

2) Avoid using alcohol-based, amido or acetone-based detergents

3）The casing of the oximeter should be kept from the contamination of filth and dirt, and it can be wiped with non-velvet soft cloth. When cleaning, do not spill the liquid onto the instrument. Ensure no liquid is allowed to enter the inside of the oximeter. There are some cable sockets on the side panel of the oximeter, and when doing cleaning extreme caution should be exercised and make sure no water can enter them.

4）It is forbidden to use such grinding materials as wire brush or metal polishing agent, because these materials may cause damage to the panels of the oximeter.

5）Please do not soak the oximeter in liquid.

6）When the plugs and connectors of the cables or accessories are wetted, please rinse them with distilled water or deionized water and then leave them in the environment of 40°C to 80°C to dry for at least one hour.

7)Under normal circumstances, it is not necessary for the oximeter to have special maintenance, and cautions must be exercised on the following points during the use of the oximeter:

- Please use the oximeter in the environment according to the requirements of the performance criteria;
- Avoid exposure or direct sunlight.
- Avoid excessive radioactive infrared rays or ultraviolet rays.
- Avoid contacts with organic solutions, dusts or corrosive gases.

6.2 Oximeter Sensor

1) The casing of the sensor and light tube can be cleaned with swab or non-velvet soft cloth dipped with medical alcohol.

2) The sensor cable can be cleaned or sterilized with Hydrogen Peroxide 3% or lsopropylalcohol 70%.

3）It is forbidden to put the oximeter in high-pressure containers and put the sensor directly in liquid.

Warning: When the oximeter is not in use for a prolonged period, the batteries in the battery case must be removed and stored properly.

Warning: Disposable Oximeter sensors must not be re-sterilized or reused.

6.3 Sketch Map of electrical Mechanism

Sketch map of electrical mechanism and component list are only provided to the approved maintenance stations or personnel authorized by our Insitutite.

6.4 Troubleshooting

Warning: There are no user-serviceable parts inside the oximeter. The cover should only be removed by qualified service personnel.

Warning: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the oximeter is functioning correctly.

Caution: Do not spray, pour, or spill any liquid on the oximeter, its accessories, connectors, switches, or openings in the enclosure as this may damage the oximeter.

6.4.1 Possible errors and proposed disposals

List of possible errors and suggestions for correcting them.

Errors	Possible causes	Disposals
There is no response to the Power button.	The button can not be pressed to its position	Ensure that the Power button is fully depressed.
	Battery capacities are low	The batteries may be missing, discharged, or oriented incorrectly. Replaced them with new ones.
	Errors of internal data	Remove one of the batteries and install it again in several minutes.
One or more display segments or indicators do not light during the power-on-self-test.	Components of the oximeter may have been damaged.	Do not use the oximeter; contact qualified service personnel or your local Nellcor Representative.

The PR search time is too long	The sensor used is not compatible.	Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and extension cable connections. Test the sensor on another subject.
		Let another person try or try another sensor or extension cable.
	Perfusion may be too low	Check the patient. Test the oximeter on yourself. Change the sensor site. Try another sensor.
	Patient movement	Interference due to patient activity may be preventing the oximeter from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site.

The PR search time is too long	The sensor may be too tight, there may be interference due to ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.	Reposition sensor, as necessary.
	Electromagnetic interference may be preventing the oximeter from tracking the pulse.	Remove the source of interference.
In continuous measurement, sometimes there are no measuring data.	Battery voltage is insufficient	Change batteries (when they are too weak, change them)
	The sensor is not positioned properly.	Reposition sensor, as necessary.
	Insufficient blood supply.	Check the patient. Test the oximeter on yourself. Change the sensor site. Try another sensor.
After start-up, it is not possible to enter normal measuring status.	Start-up errors.	Restart the oximeter
	Battery capacities insufficiency	Battery capacities insufficiency may lead to abnormal start-up.
After start-up, the oximeter cannot operate normally and it cannot be switched off normally.	Program error	Switch off the power and install the program again
	Battery capacities are two low	replace them with new batteries

6.4.2 EMI (Electromagnetic Interference)

Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments, it is possible that high levels of such interference due to close proximity, or strength of a source, may result in disruption of performance of this device. Examples of noise sources in healthcare environments that could cause electromagnetic interference are:

1) Electrosurgical units
2) Cellular phones
3) Mobile two-way radios
4) Electrical appliances
5) High-definition television

The oximeter is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the oximeter may not seem to operate correctly. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions should be taken to eliminate the source:

1) Turn equipment in the vicinity off and on to isolate the offending equipment.

2) Reorient or relocate the interfering equipment.

3) Increase the separation between the interfering equipment and this equipment.

The oximeter generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with these instructions, the oximeter may cause harmful interference with other devices in the vicinity.

6.5 Periodic Safety Checks

The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

* Inspect the equipment and accessories for mechanical and functional damage.
* Inspect the safety relevant labels for legibility.
* Verify that the device functions properly as described in the instructions for use.
* Test the enclosure leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995:
Limit: NC 100 uA, SFC: 500uA.
*Test the patient leakage current from the applied part to the enclosure of internally powered equipment according IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 100 uA, SFC: 500uA.
*Test the patient leakage current via an F-type applied part to the enclosure according IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: for NC 100 uA, SFC: 500uA.
The leakage current should never exceed the limit.

The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

6.6 Warranty Provisions

1) When the user begins to use the oximeter, the user should fill out the various contents of the warranty card and timely mail it back to our Company; based on this, our Company shall establish user files and will regularly learn about the use status; this will enable the Company to provide our users with continuous and pinpointed quality service.
2) Under the circumstance of normal use according to the use instructions and operational precautions, in case troubles occur, please contact the Technical Service Center of our Company immediately. Based on the time limit and conditions indicated below, from the time of purchase, the user is entitled to free warranty services within one year.

3) Our Company may execute our warranty pledges through such means as visits, telephone guidance and couriering device back to our Company.

4) Even within the free warranty period, the following maintenance may be charged:

① Troubles or damages caused by improper use by users.

② Troubles or damages due to falls during handling after purchase.

③ Troubles or damages caused by repairing, remodeling or dismantling at locations outside the Company.

④ Troubles or damages caused by fire, natural disasters, earthquakes after purchase.

⑤ Troubles or damages due to the fact that the company failed to use of the SpO_2 probe designated by our Company.

⑥ Troubles or damages caused by connections to other electrical equipment.

⑦ If the warranty seal is broken, or corrected without authorization; the serial numbers of the oximeter and probe are replaced by the user.

5） In case this product has trouble within three months, if it is not due to the causes listed in Clause ④, our Company shall be responsible for replacing the oximeter free of charge, but accessories, reconditioning components and consumables are not entitled to replacement.

6）Our Company shall not be held liable for any trouble of other connected appliances which are directly or indirectly caused the trouble of this product.

7）This warranty system is valid within China.

8）In case the warranty label is found to have been damaged, our Company has the right to waive the one-year free maintenance service.

9）Regarding the charged repairs and maintenance beyond the warranty period, it is advised to use "Maintenance Contract System", and please contact our Company for details.

Chapter 7 Specifications

7.1 Performance

SpO_2:	
Measuring Range	0~100%
Resolution	1%
Accuracy	At 70~100%, ±2% At 0~69%, unspecified
Data update period	<13 seconds

PR:	
Measuring Range	25~250 bpm
Resolution	1 bpm
Accuracy	±2% or ± 1 bpm, whichever is greater
Data update period	<13 seconds

7.2 Electrical

Type	Voltage
4 AA alkaline	6 Volts DC (as per 4 AA batteries)
The oximeter uses four 1.5 V AA type batteries and a set of new batteries can be used for a continuous period of 10 to 24 hours, depending on concrete battery types.	

7.3 Environmental Conditions

Operation:

Temperature	5℃～+40℃
Atmospheric Pressure	860hpa～1060hpa
Relative Humidity	≤85% (no condensation)

Transport and Storage

Temperature	－20℃～＋55℃
Atmospheric Pressure	500hpa～1060hpa
Relative Humidity	≤93%(no condensation)

7.4 Physical Characteristics

Weight	0.125Kg
Dimensions	141mm × 74mm ×27mm

7.5 Sensors

Wavelength	pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm. The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy. **Note:** Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001. No special safety precautions are required.

7.6 Classification

Type of protection against electric shock: Internally powered equipment;
Degree of protection against electric shock: Type BF applied part;
Classification according to the degree of protection against ingress of water: Ordinary;
Equipment is not suitable for use in the presence of flammable mixtures.

Chapter 8 Accessories

Accessory	Description
SpO2 sensor (Reusable)	Ear Clip sensor (5Pin)
	Tongue clip

Appendix A: Guidance and Manufacture's Declaration of EMC
Guidance and manufacturer´s declaration – electromagnetic emission –for all EQUIPMENT AND SYSTEMS

<table>
<tr><td>1</td><td colspan="3">Guidance and manufacturer´s declaration – electromagnetic emission</td></tr>
<tr><td>2</td><td colspan="3">The HANDHELD PLUSE OXIMETER is intended for use in the electromagnetic environment specified below. The customer or the user of HANDHELD PLUSE OXIMETER should assure that it is used in such an environment.</td></tr>
<tr><td>3</td><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>4</td><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The HANDHELD PLUSE OXIMETER uses RF energy only for its internal function. Therefor, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>5</td><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The HANDHELD PLUSE OXIMETER is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>6</td><td>Harmonic emissions
IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>7</td><td>Voltage fluctuations /flicker emissions</td><td>N/A</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The HANDHELD PLUSE OXIMETER is intended for use in the electromagnetic environment specified below. The customer or the user of the HANDHELD PLUSE OXIMETER should assure that it is used in such an environment.			
Immunity test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	N/A	N/A	N/A
Surge IEC 61000-4-5	N/A	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input	N/A	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity –for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><td colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The HANDHELD PLUSE OXIMETER is intended for use in the electromagnetic environment specified below. The customer or the user of HANDHELD PLUSE OXIMETER should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>N/A</td><td>N/A</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the HANDHELD PLUSE OXIMETER, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m 80 MHz to 2.5 GHz</td><td>3 V/m</td><td>$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)b.</td></tr>
</table>

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HANDHELD PLUSE OXIMETER is used exceeds the applicable RF compliance level above, the HANDHELD PLUSE OXIMETER should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HANDHELD PLUSE OXIMETER.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the SL-F SL Series Anti-decubitus Mattress

The HANDHELD PLUSE OXIMETER is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HANDHELD PLUSE OXIMETER can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HANDHELD PLUSE OXIMETER as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	1.2	0.12	0.23
0.1	3.8	0.38	0.73
1	12	1.2	2.3
10	38	3.8	7.3
100	120	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Product name: Veterinary Pulse Oximeter

Product type: M700VET

Address: No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai , P.R.China

Post code: 519085

PN: 22-005-0003